UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	November 17, 2017

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

MOTION HEARING AND SCHEDULING CONFERENCE

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14:56:52 1 **P R O C E E D I N G S**

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3 THE COURTROOM DEPUTY: In the matter of MDL

4 2015-2641, Bard IVC Filters Products Liability Litigation, on

13:01:36 5 for a motion hearing.

6 Will the parties please announce.

7 MR. LOPEZ: Good afternoon, Your Honor. Ramon Lopez

8 on behalf of the plaintiffs' leadership committee.

9 MR. O'CONNOR: Good afternoon, Your Honor.

13:01:45 10 Mark O'Connor for plaintiffs' leadership committee.

11 MS. REED ZAIC: Good afternoon, Your Honor.

12 Julia Reed Zaic on behalf of plaintiffs' leadership committee.

13 MR. NORTH: Good afternoon, Your Honor.

14 Richard North on behalf of the defendants, and I have with me

13:01:55 15 from my office Elizabeth Helm, James Rogers, Matthew Lerner.

16 We also have Amanda Shelton from Snell & Wilmer. And we also

17 have Candace Camarata, the assistant general counsel for Bard

18 and defendants today.

19 THE COURT: All right. Good afternoon, everybody,

13:02:16 20 and welcome to the folks on the phone.

21 We are here to argue the summary judgment motion on

22 preemption and the summary judgment motion in the Booker case,

23 and then to discuss some case management issues.

24 Counsel, what are your thoughts on how you want to

13:02:30 25 argue it and how much time you think it will take? That is,

13:02:33 the motions. What are your --

MR. NORTH: Your Honor, since we're the movant in both, we're here at the Court's discretion, whatever the Court would find helpful. We're prepared to make an argument on
13:02:47 both motions, I would say 15 to 20 minutes each, or we can just answer questions. Whatever the Court would prefer.

MS. REED ZAIC: I would agree with that, Your Honor. Our responses will heavily be weighted towards what we might have to respond to, of course, and the Court's questions.

13:03:04 THE COURT: Well, why don't we go ahead and have you make the arguments you wish to. I'll ask questions as I see fit, and then we'll allow the plaintiffs to respond. 15 to 20 minutes per motion is fine.

I've read the motions. I've read the major cases
13:03:22 cited in the motions. I've not read all of the cases. So I'm familiar with the arguments. And you don't need to sort of educate me on the arguments. I think I know the issues on each of the points that are briefed.

Why don't we deal with the general preemption motion
13:03:40 first, argue that, and then deal with the Booker motion.

So, Mr. North, whoever would like to go from your side, let's get started on that.

MR. NORTH: Thank you, Your Honor.

May it please the Court.

13:03:56 This motion, based on federal preemption, admittedly

13:03:59 presents a paradox, we believe. On the one hand the applicable legal precedent is well established with cases that this Court has often considered in your past decisions. Although, as some courts, including the Tenth Circuit, have 13:04:13 noted recently, this precedent perhaps requires revisiting and reconciliation. But regardless, the precedent is clear, particularly with *Riegel* and *Lohr* as the main two cases. What is not precedented, we submit, is the factual record presented in this case.

13:04:32 In scouring the federal authorities, we have not found a single case that presents an instance of such a rigorous review by the FDA of a 510(k) product. In fact, there may not be any comparable scenarios out there where the FDA has conducted such an extensive and elaborate review of a 13:04:54 510(k) device. But despite this paradox, we believe the issues before the Court are relatively straightforward. They are two.

First, can preemption even apply under the medical device amendments, the MDA, to a 510(k) product, and if so, 13:05:11 can it apply and should it apply to the record that Bard has presented in this case?

The plaintiffs seem to suggest in their brief that there is a categorical preclusion about applying preemption to a 510(k) product. Particularly in their brief at page 20 and 13:05:30 footnote 19, they say that "fundamentally" -- and I'm

quoting -- "fundamentally a 510(k) product is equivalence not safety review and thus cannot preempt plaintiffs' claims," suggesting to this Court, at least implicitly, that under no circumstances can there be preemption with a 510(k) product.

We respectfully submit that is not the law.

Only a plurality in the *Medtronic versus Lohr* case seem to base its no preemption decision on the nature of 510(k) review. And even that plurality disclaimed the notion that general standards could never preempt state law claims.

And the court emphasized that, the Supreme Court did in *Riegel*, that even the plurality disclaimed a categorical rule.

In *Medtronic versus Lohr*, the fifth concurring justice, Justice Breyer, the justice that gave the majority for finding no preemption in that case, did not base his decision whatsoever on the 510(k) nature of the review. Instead, he based his decision on the absence in that particular case of any specific requirements for the device at issue.

THE COURT: Let me ask you this question, Mr. North: What do I do with Justice O'Connor's opinion that said 510(k) would not preempt? Do I add that to the plurality? I know she found preemption on the basis of broader statutes, which wasn't adopted by a majority, but she said in her opinion a 510(k) would not preempt. Do I count that when I'm counting

13:07:15 noses, if I should be counting noses, in the *Lohr* case?

MR. NORTH: Well, I think you can't, Your Honor, because later in the *Riegel* case, and admittedly the cases and the opinions are all over the place on this subject, later in 13:07:27 *Riegel* the clear five justice majority, including Justice O'Connor, noted that in *Lohr* even the plurality disclaimed an application that the notion that general standards could never preempt.

And so here we have a case where we don't mind if it 13:07:42 had just general standards at play, we have very specific standards. And I think that you have to look at Justice O'Connor's dissent, her comments in the dissent there, which I believe was directed, if I recall correctly, only to the negligent design claim in that particular instance, but 13:08:00 you have to look at it through the light of *Riegel*, where she joined the majority, and those same dissenters joined the majority noting that even in *Lohr* there was not a categorical rule.

The Ninth Circuit has also disclaimed any categorical 13:08:17 prohibition of preemption in the 510(k) context. The *Papike* case, which involves tampons, a Class II device, the court in that case noted that there were specific requirements applicable to that Class II device, and as a consequence in that particular case, those requirements were preemptive of 13:08:40 any statement law tort claim.

13:08:44 And then, of course, this Court is familiar with Ninth Circuit's decision in *Degelmann*, which of course was later vacated and therefore is not precedent, but it is instructive because it also follows the same reasoning as 13:08:55 *Papike*. In that case once again the Ninth Circuit suggested there is no categorical prohibition of preemption in the 510(k) context. Instead, they recognized in that case that the existence of a very specific guideline applicable to the specific device could be preemptive.

13:09:17 Admittedly, some district courts have suggested out there that there is a categorical prohibition. But we would suggest that that's inconsistent with what the Supreme Court actually said in *Lohr* and *Riegel*. It is inconsistent with what the Ninth Circuit has said in *Papike*, which is precedent, 13:09:36 in *Degelmann*, which is at least instructive, and it's inconsistent with what Justice -- now-Justice Gorsuch recently commented before his elevation to the Supreme Court in the *Caplinger* case on behalf of the Tenth Circuit. In suggesting that the precedence needed to be reconciled, he said that it 13:09:53 appears under the MDA that preemption is appropriate if there is premarket approval, PMA review, or something like it.

In other words, if there is, as the Ninth Circuit has suggested in *Papike*, a specific standard applicable to a specific device.

13:10:17 If you accept the premise there is no categorical

13:10:20 preclusion of preemption to a 510(k) device, the question becomes does it apply in this instance. This Court has already articulated, of course several times, in cases such as *Arvizu* and *Thibodeaux*, what the standard is.

13:10:44 The standard is based on the preemption clause of the MDA. 21 U.S.C. Section 360. And under that clause, the standard is whether -- number one, whether the federal government has established requirements applicable to a specific device; and, two, whether state claims impose

13:11:06 requirements that are different from or in addition to federal requirements regarding the safety and effectiveness of the device.

Now, that's exactly what has happened here, we submit.

13:11:18 The FDA has enacted a regulation 21 CFR 870.3375, which identifies special controls for filters. First it identifies an ISO standard regarding biological evaluation of medical devices; and, second, it identifies a Sterility Review Guidance.

13:11:43 Now, admittedly, Your Honor, those first two guidances are more akin to the sort of standards referenced in *Lohr*. The more general standards. But the third item it references is an IVC Filter Guidance, and that provides the specific standard in this case.

13:12:14 In this standard, Your Honor, the plaintiffs attempt

13:12:18 to paint it as aspirational and maybe just a suggestion by the FDA. We submit it is anything but. It says that either you must comply -- it says "you must comply with these specific recommendations of this guidance or provide the agency with 13:12:39 some alternate control that provides equivalent assurances of safety and effectiveness." Either/or. It's not telling you exactly how your test protocol must be done, but it's telling you what issues regarding the safety and effectiveness of the device you must do.

13:12:58 And it's not saying you should consider it, it's saying "you," and I quote, "should demonstrate that the proposed device complies with either these specific recommendations or some alternate control that provides the same assurance."

13:13:14 And what are some of those considerations that the FDA is requiring compliance with?

The plaintiffs suggest that this guidance document is really just a pathway for a manufacturer to show equivalence. Just simple comparative similarity to a predicate device. To 13:13:38 the contrary, it outlines a number of aspects going to the heart of the safety and the effectiveness of the device.

It requires certain evaluations of simulated deployment, which pertains both to safety and to effectiveness. It requires assessments of the introducer 13:14:01 sheath suitability of the device.

13:14:03 It requires testing and assessment of the clot trapping ability of the device.

Clearly going to the effectiveness.

And it wants and requires an evaluation of many 13:14:15 aspects of safety regarding the filters, including filter fracture, caval perforation, filter migration, thrombogenicity, MRI compatibility. These issues do not have to do with equivalence, Your Honor. They strike at the heart of the same sort of concerns that underlie PMA review, the 13:14:38 safety and effectiveness of the device.

And the FDA specifically decided this device -- or this guidance was necessary to ensure the safety and effectiveness.

According to the FDA memos that we have obtained, 13:15:00 when the filters were being reclassified from Class III to Class II, which eventually went into effect in 2000, the agency noted that special controls in the form of standardized labeling and a device guideline on vena cava filters have been developed. And those controls provide reasonable assurance of 13:15:23 the safety and effectiveness.

The agency specifically determined that these -- this filter guidance was going to demonstrate to it safety and effectiveness. Not just substantial equivalence.

Now, we can't in this case, we submit, though, focus 13:15:49 only on the guidance in a vacuum. We have to look at the

13:15:52 extensive record of how the FDA for more than 15 years has applied that guidance to Bard filters.

And we submitted the lengthy declarations of Rob Carr and John Van Vleet, two gentlemen employed by Bard who were on 13:16:09 the front lines dealing with the FDA day in and day out regarding these filters.

We submit that this sort of record showing the day to day, month by month involvement of the FDA, its review, is unprecedented. Again, we have not been able to find a single 13:16:31 preemption case that demonstrates this sort of factual record.

And this record has not been challenged by the plaintiffs. They have quibbled with the meaning of what's there, but they have not disputed the occurrence of these events.

13:16:47 What does that record show? It shows that the FDA with regard to Bard filters has required three clinical trials: One with the Recovery filter, one with G2 filter, and one with the Denali filter.

The plaintiffs try to dismiss those clinical trials 13:17:05 as not particularly relevant saying that, Well, they were just designed to look at retrievability.

Well, regardless of whether they were looking at retrievability, they were also, as required by the FDA, cataloging and reporting all adverse events. And they were 13:17:22 reporting that data to the FDA. And the FDA was getting

monthly reports on those tests, of the clinical studies, about the adverse events.

The *Horn* case from the Third Circuit is a PMA preemption case, but it talks in terms of why there is preemption for PMA devices on the importance of the FDA's requirement for clinical studies, just like you had here.

An important point that I think distinguishes filters from the vast magistrate majority of 510(k) devices is the fact the statistics show that clinical studies are required by the FDA in less than 8 percent, around 8 percent of 510(k) devices. This is a very unusual situation where the FDA has very proactively required certain instances.

The record also demonstrates that the FDA was constantly requesting additional information. It was not a matter of, okay, Bard submits the test results required by the guidance and the FDA rubber stamps. Beginning with the Recovery filter from the very first 510(k) submission, the FDA came back with lengthy questions delving into numerous aspects about the testing that had been performed, and the vast majority of the FDA's inquiries went directly to the heart of the safety and effectiveness of the device, and not focused on equivalence. And that pattern continued. Continued through the G2. It continued through the Eclipse. The Meridian, back and forth, went over a year where the FDA kept going back for more data, more tests, more refinement of how the filter was

13:19:13 being evaluated. All for the purpose of assessing safety and effectiveness, not equivalence.

With the Denali, the FDA said, you're going to have to do this clinical trial before you can even sell this filter 13:19:30 as a permanent device.

And they make a big point of, well, that clinical trial wasn't finished when the Denali filter was cleared. Well, no, because the FDA said, we will not accept your 510(k) submission -- and this is in the record -- until you have 13:19:44 enrolled 100 patients in this trial, until you have followed those 100 patients for six months, and until you have retrieved 45 filters. At that point you may submit with that data from that part of the test, submit your 510(k), which is what we did. The study continued and wrapped up later, but 13:20:06 the FDA had that safety and effectiveness data when making its determination.

The record also shows multiple demands by the agency regarding labeling, requiring specific language. They say that's negotiation back and forth. Well, certainly sometimes 13:20:26 the FDA said, we want you to put X, and we said, well, what about Y, and the FDA might agree or might not agree. But ultimately the FDA was controlling every step of the way what we did.

And I think perhaps the best example of this happened 13:20:42 in August of 2004. At that time the Recovery filter IFU did

not have a fracture warning. Bard wanted to add one, and the record, in the declaration of Rob Carr, shows this.

We called the FDA and we said, hey, just for your knowledge, we are going to change the IFU to add this warning and we're going to send out a dear doctor letter. And the FDA said, whoa, whoa, whoa, we want to see this first and determine whether you need to submit a new 510(k).

So we sent the package to the FDA. The FDA spent three months reviewing it, and then around Thanksgiving of 2004 the FDA came back and said, okay, we're going to allow you to go forward with the revised IFU and you may send out the dear doctor letter, but we want certain changes in the dear doctor letter.

Again, they're looking at this device and the labeling for safety and effectiveness, not for substantial equivalence. And, in fact, those declarations and the communications back and forth with the FDA are replete with the FDA expressing issues focused directly and like a laser on safety and effectiveness with this device.

In *Riegel*, the Supreme Court said that PMA review is preemptive for a PMA device because it is in essence federal safety review.

We submit, Your Honor, the IVC filter guidance document developed by the FDA as applied to Bard's filters by the FDA over 15 years, and shown in these declarations, show

13:22:33 the same thing, this is federal safety review and always has been.

We believe that as a result, the FDA's extensive regulations, extensive review of safety and effectiveness 13:22:50 should be preemptive of the plaintiffs' claims.

Now, we recognize in the Ninth Circuit there is an exception growing out of *Riegel* for parallel claims. I think it's based on the *Stengel* case en banc from the Ninth Circuit. It is possible that some of their claims arguably could be 13:23:07 carved out, but they've not argued that, Your Honor. They did not even respond to the motion trying to point out any parallel claims, and I'm not sure that I've seen any that have been asserted in this particular case that are parallel.

So as a consequence, as we pointed out in great 13:23:24 detail in our briefs in citing cases, we believe that each of their claims should be preempted.

In conclusion, Your Honor, we believe this is an unprecedented case. There are precedents to apply, and those precedents say that there is no categorical prohibition of 13:23:42 preemption in a 510(k) context.

But this case is unprecedented because of the record that has been demonstrated. It may be unprecedented in the level of the FDA's review of a 510(k) device in the first instance. But regardless, this is tantamount to federal 13:24:00 safety review, just as in the PMA context, and on that basis

13:24:04 we believe there should be preemption.

Thank you.

THE COURT: Okay. Thanks Mr. North.

Plaintiffs' argument.

13:24:54 MS. REED ZAIC: Your Honor, I have a PowerPoint that I -- I'm not giving out a precopy -- I have a precopy if you'd like to follow along, or your clerk, and to provide to defense counsel. My concern is if I provide it and don't use all my slides, if I could -- if the Court would like to hang on to it

13:25:09 I can provide a final --

THE COURT: I don't need a copy, but if you want to give a copy to --

MS. REED ZAIC: You don't need a copy, I'm sorry, Your Honor?

13:25:16 THE COURT: I do not. But why don't you give a copy to defense counsel.

MS. REED ZAIC: Apologize to the Court. Hopefully that won't happen again.

Again, apologize to the Court.

13:26:14 Your Honor, defendants' motion be denied for several reasons. To start with, there is no evidence that this case is unprecedented in its factual record, special controls, guidance documents, or anything else. There's no evidence that Bard has demonstrated how it has allegedly conducted an

13:26:31 extensive IV filter regulatory history and how that differs

13:26:35 from other 510(k) devices that have been cleared to market.

There's no evidence that its 510(k) reviews resulted in something like PMA approval, and they are actually forbidden from making that representation.

13:26:48 There is no evidence that Bard's 510(k) endured rigorous review like PMA review. In fact, what they presented so the Court is only a protracted reenactment and a blow by blow of all of their communications under a regulated environment under which the 510(k) rules and regulations

13:27:07 apply.

There's no evidence of a modern, or now what they have called in their reply brief a now superseded, 510(k) process that's contrary to Supreme Court holdings in *Lohr* and *Riegel*, and causing *Lohr* to be outdated or overruled.

13:27:27 Bard also fails to address the express preemption test. It focuses on its alleged unprecedented 510(k)'s rather than actually evaluating the facts under 360(k), which is the express preemption clause.

They also did not evaluate the facts under 21

13:27:42 CFR 808.1(d), which limits the scope of the express preemption clause under the MDA.

And Bard is also engaged in improper burden shifting with regard to the burden that plaintiffs have. Plaintiffs do not, for example, have the burden to negate Bard's allegations

13:28:01 of uniqueness or modern 510(k) processes, arguments that

13:28:06 compare to other 510(k) applications, which they have not presented to the Court.

I want to start with the basic concept. I understand the Court's admonition that you've read the case law, but this 13:28:19 is extremely important, I believe, to our opposition.

The difference between "approval" and "clearance." These two words are often interchanged, interjected in the inappropriate circumstances by lawyers, including myself, in judicial opinions. Sometimes PMA approval is also -- I'm 13:28:39 sorry, the word "approval" is used with 510(k) clearance when it should be limited to premarket approval applications, and the FDA is clear, even on their website, that approved medical devices are those devices for which FDA has approved a premarket application prior to marketing.

13:28:58 And "cleared medical devices" are medical devices that FDA has determined to be substantially equivalent to another legally marketed device, and a premarket notification, referred to as the 510(k) process, must be submitted in advance.

13:29:18 The basis of Bard's argument that the *Lohr* case -- or the FDA process after 1990 has been superseded lies in the history of the Medical Devices Act to begin with. In 1976, when it was promulgated, it included performance standards. And no one on the plaintiff side is going to come into court 13:29:39 and say that the medical devices amendments or the FDCA at all

13:29:44 has nothing to do with safety. Safety underlies these acts. *Lohr* says it via the Supreme Court's interpretation of it.

But in 1976, when there were performance standards required of all medical devices, it was impossible for the FDA 13:29:58 to comply with that standard. A performance standard for every medical device would require research and review of every device establishing these standards for every single device the agency oversaw. That became impossible. And in 1990, there were further amendments to the Medical Devices Act 13:30:15 via the Safe Medical Devices Act of 1990.

In this act, special controls replaced performance standards. They are less specific. Special controls can be any document or information that the FDA cites and identifies associated with devices.

13:30:35 Special controls are not a tool for express preemption and to evaluate whether claims against a medical device are expressly preempted. They're for regulatory purposes. And the special controls assigned, as Mr. North indicated, are at 21 CFR 870.3375 and consist of three 13:30:56 guidance documents, one of which seems to be at issue here now that I've heard counsel say that the first two admittedly aren't as applicable to their arguments.

Mr. North covered the actual express preemption clause. He did not cover the regulation that has since 13:31:13 narrowed it. *Lohr* and *Riegel*, the Supreme Court tells us that

13:31:16 the FDA has given wide latitude with regard to the FDC -- the medical device amendments with regard to the express preemption clause.

And CFR 808.1(d) says state or local requirements are 13:31:30 only preempted when the FDA has established specific counterpart regulations or specific requirements applicable to a particular device.

The express preemption clause did not change between 1976 and 1990, and neither has this regulation. That is the 13:31:48 test that has been employed by the Supreme Court and courts long afterwards in evaluating this issue when it comes to 510(k) devices.

I understand the Court has -- of course is familiar with the major case law, as Your Honor has stated, but I just 13:32:05 want to cover a couple of points here that will be applicable in my opposition.

510(k) is focused on equivalence, not safety. That is from the Supreme Court in *Lohr*. It is not overruled. It still applies regardless of defendants' claims it is 13:32:20 superseded at this point because of some modernization or change to the 510(k) process. It does not require the device take a particular form. It is general. That's why in *Lohr* and *Riegel*, *Riegel* upholding *Lohr*, the statute itself and the regulations are general controls.

13:32:38 And 510(k) devices can be marketed without running

13:32:41 the gauntlet of PMA because it's an exception to the premarket approval process. There is no suggestion in either the statutory scheme or the legislative history that the 510(k) exception process -- exemption process, pardon me, was 13:32:54 intended to do anything except maintain the status quo. And the status quo included the possibility the manufacturer of the device would have to defend itself against state law claims of negligent designs. Design.

This is a comparative process. And as I mentioned 13:33:10 before, no one is going to claim here that the MDA has nothing to do with safety and effectiveness. *Lohr* actually tells us the MDA was enacted to provide for the safety and effectiveness of devices intended for human use.

The 510(k) process, the Supreme Court tells us, is 13:33:30 device specific. But that doesn't mean there's a focus on safety and effectiveness. The review does not require 510(k) devices again to take any particular form for any particular reason. This is why there was no preemption in *Lohr* based on the concept of general controls and lack of specificity 13:33:47 between the statute and the regulations unless there was a specific aspect to it.

That's why the holding was that 510(k) imposed no device-specific requirements and did not implicate the express preemption clause.

13:34:02 And *Riegel* upheld all of this.

13:34:11 Bard alleges that *Lohr* is superseded. They have no authority to make that statement. There are a few different cases that have been brought recently, since 2014. Actually a total of four. I make that representation with a little 13:34:26 hesitation because I cannot say that I have reviewed all 13,000 times that *Lohr* has been cited. But since Bard argues the SMDA overhauled the MDA when it actually relaxed standards, overhauled the MDA and *Lohr*, it's important to point out that *Lohr* was -- was -- the -- strike that.

13:34:48 The issue in *Lohr* and the decision was six years after the SMDA was enacted. And the sweeping language of *Lohr*, later upheld by *Riegel*, did not indicate anything that the defendants are saying, and the Court certainly had the opportunity.

13:35:04 Now, *Lohr* is the law of the land. I don't think there is a dispute to that. It has been cited over 13,000 times. 2,018 of those citations are judicial opinions. It has been cited 109 times in 2017 alone. And two months ago I argued -- I opposed the same motion in the Cook MDL, and it's 13:35:25 been cited 23 times since then, just two months ago.

There have only been four times -- and again not my extensive search of all 2,000 of these judicial opinions, but hundreds of them. I've only found four instances where someone has come forth and made this argument that *Lohr*'s 13:35:42 outdated and superseded or there's been some overhaul or

13:35:45 modernization to the 510(k) process. Three times the argument was made by Cook, the other IVC manufacturer for which there is an MDL in the Southern District of Indiana.

Two of those opinions involved a similar -- excuse 13:36:00 me -- the same law review article that Bard cites. They did not deal with IVC filters. The third argument by Cook did deal with the IVC filters that I mentioned two weeks ago, and the fourth one is Bard bringing the argument again.

The *Horrillo* case is representative of other courts, 13:36:21 although not binding on this Court. It's almost an exact replay or deja vu of what we have seen here. Defendant argues the FDCA's express federal preemption provision should apply to plaintiff's stent, or the product, because the stent was approved under a revised, more rigorous version of the 510(k) 13:36:51 process, which did, in fact, made a safety and effectiveness determination.

I'll provide you a copy of my PowerPoint, madam court reporter. I apologize.

Essentially defendants argue that the analysis set 13:37:06 forth in *Lohr* is outdated and should not apply to plaintiffs' claims because the medical device at issue in that case was approved under the 510(k) process as it existed in 1982, which should not make a safety and effectiveness determination. This is the same argument Bard is making.

13:37:22 Defendant also argues that the FDCA's express federal

preemption provision should apply to plaintiffs' claims because the revised, the claim, the alleged revised 510(k) process which arose out of Congress's passage of the Safe Medical Device Act in 1990, is more akin to the premarket approval process.

That summarizes part of Mr. North's argument that he's made here today.

The result of that case, *Horrillo v. Cook*, in 2014 is that the motion was denied, and the reasoning was a cite from a law journal article, the same one that Bard had cited. Defendant does not cite any legal authority to support this argument, nor has defendant presented sufficient evidence to support this argument. And although the argument raises an interesting issue, this court does not find that it has the authority to arrive at a ruling contradictory to *Lohr* or *Riegel*.

Very similarly, in 2015, the same argument was made again by Cook in the transvaginal mesh case. I will not go through and quote this exactly, except that Judge Goodwin found that "the arguments raised by Cook do not persuade me to abandon the Supreme Court's clear position on this matter."

And that the FDA's 510(k) review continues to primarily focus on equivalence as opposed to safety, and as a result, I'm doubtful that the Supreme Court would change its clear position on this matter based on the SMDA. In fact, any

13:38:51 changes imposed by the SMDA, which had already been in place for six years at the time of the *Lohr* decision, were available to the court in interpreting Congress's intent for 510(k).

Our position is the same, Your Honor.

13:39:09 The sweeping language of *Lohr* and *Riegel* show that the Supreme Court was aware at the time in 1996 of things like special controls and they still issued the sweeping language they did about 510(k) and the express preemption clause.

The ruling in the Cook MDL two months ago was that 13:39:32 the motion was denied, and Judge Young said to me, "Just to give you a preview here of my thoughts on preemption, I believe the law is clear on the subject *Lohr* is Supreme Court law at this time."

Bard has taken time in its papers and its oral 13:39:56 argument today to point out to the reclassification process that occurred with IVC filters, and that process did take place. Originally IVC filters were Class III devices. Information was gathered by the FDA to indicate and learn and decide should it remain a Class III device. They chose to 13:40:13 down-classify it. But this is of no particular moment to a preemption argument.

Under 21 CFR 807.97, reclassification is treated the same as pre-MDA, pre-1997 -- 1976 devices. In fact, the regulation says submission of a premarket notification or a 13:40:33 510(k) and a subsequent determination by the commissioner that

"the device is substantially equivalent to a device in commercial distribution before May 28, 1976, or a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into Class I or Class II does not in any way denote official approval of the device."

When the FDA is issuing substantial equivalence decisions on products coming to them via the 510(k) process, they do not make a distinction. It is substantially equivalent to either one or the other.

On that note, the reclassification memo that Bard has submitted as Exhibit H to their reply papers, which was downloaded from the Cook MDL site, it's actually a new argument they've made in their reply papers, this classification and the significance, or potential and alleged significance of it, that memo was -- the information for it was gathered and was drafted by the FDA prior to retrievable filters even being on the market.

Bard has claimed that because it was asked by the FDA or on its own submitted clinical trial data as part of its 510(k) packages, that it is somehow akin to a PMA approval application and should enjoy the protections of the express preemption clause.

But the FDA, in the course of 510(k) review, can request any information that it wants. This is part of the

13:42:08 general controls explored in *Lohr* and *Riegel*.

In fact, a request for additional information will advise the manufacturer there is insufficient information contained in the original premarket notification submission, 13:42:22 and the manufacturer may either submit the requested data or a new premarket notification containing the requested information can be submitted. If the additional information is not submitted within 30 days following the date of the request, the commissioner will consider the premarket 13:42:39 notification to be withdrawn.

This is the bulk of the factual record presented to this Court, is the back and forth descriptions, the letters, the e-mails, the contact, the submissions themselves that frankly -- and I'm not trying to make a joke out of this, but 13:42:56 honestly I'm surprised there are not paper cuts right now because of the 818 facts that have been submitted and the blow-by-blow reenactment of each one of these applications that were submitted, and when the FDA requested more information and Bard's attempts to provide it.

13:43:11 This was all within the 510(k) process. It was all to establish substantial equivalence. Completely separate from approved devices under a PMA process and the 510(k) process. In fact, although those regulatory pathways can be close in the sense that, yes, they're part of the same act, 13:43:32 these are medical devices and the FDA has a responsibility to

13:43:37 review for safety of devices going forward, when you look through the lens of express preemption, the PMA process and the 510(k) process have a continental divide between them.

One is based on equivalence, it's a comparative 13:43:55 process. The other process PMA looks at, as Mr. North quoted *Riegel*, it is federal safety review. It is an independent safety determination, as opposed to a review of a file that determines is this device as safe and effective as a predicate device. It's independent safety review versus a comparison.

13:44:24 Bard also furthermore claims and argues that the fact that it's submitted clinical data makes this unique. Going along and supporting the argument this is a unique situation. As I stated before, 21 CFR 807.87 allows the commissioner to ask for any additional information that he or she may choose 13:44:48 in order to complete the review of a substantially equivalent 510(k) premarket notification.

21 CFR 807.100(b)(2)(ii)(B) states that clinical data, if necessary, can be requested. In other words, starting at the top, FDA will determine that a device is 13:45:10 substantially equivalent -- again, in this 510(k) realm where the standard they have to meet is substantial equivalence -- the device has the same intended use as the predicate device, and the device has the same technological characteristics as the predicate device. Or, if it does not, if the device has 13:45:28 different technical characteristics than those of the

predicate device, the data submitted establishes that the device is substantially equivalent to the predicate and contains information including clinical data, if deemed necessary by the commissioner, that demonstrates that the device is as safe and as effective as a legally marketed device.

It does not clarify between reclassified devices, pre-1976 devices. It doesn't say the clinical data and the kind of clinical data. It says "if it is deemed necessary, the commissioner can request it for the purpose of demonstrating that safety and effectiveness is -- that the device is as safe and effective as a legally marketed device."

Again, this is *Lohr*. It is a comparison.

Getting to the factual record that Bard has submitted, I provided to the Court, and I believe it was Exhibit R but I will correct that for the record if I'm wrong, a chart of every single exhibit attached to the declarations of Mr. Carr and Mr. Van Vleet, and I broke them down into categories.

The first two categories include the submissions. There were filter submissions, specifically looking at the filter to determine if it was as safe and effective as the predicate, and in the second column there were nonfilter submissions. Those were 510(k) applications that were submitted to change something about the -- the -- potentially

13:47:02 the delivery device or the brochures involved. It wasn't actually looking at the filters.

This is not unique. This is -- this happens in every 510(k) device. Presumably the first thing that happens is you 13:47:13 have the submission. So those exhibits do not exhibit or exemplify or support the argument that this is some unique 510(k) review.

There were also letters issuing a determination of substantial equivalence. That is also part of the process.

13:47:30 There were also, six devices and 12 submissions later, several administrative communications, logistical communications such as transmittal letters of copies and things like that. Those are not unique.

Furthermore there were interactions between the FDA 13:47:59 and Bard about the general controls under the statute. Examples of these general control interactions are things such as FDA sending Bard a letter saying there was a complaint reported, we need additional information about concerning that complaint. Simply, under the regulations, following through 13:48:19 and asking questions. Nothing unique.

There were also several Bard internal notes and e-mails. These were not interactions with the FDA that set some new bar or standard to make them unique.

So what it boils down to is the communications 13:48:33 between Bard and the FDA regarding Bard's deficiencies, when

13:48:38 these requests for clinical data were made, when the request for more information that has built this alleged factual record that is so completely different than any other 510(k) for which there is no evidence in the record to show.

13:48:52 There were 17 deficiency letters sent for Bard's application -- 510(k) submissions, including filters and some including the additional submissions I noted that dealt with the delivery devices and brochures and such.

There were 33 responses from Bard. So the FDA sends 13:49:13 a deficiency letter and Bard doesn't provide the information. They have to try again, and they have to try again, and they have to try again. 33 responses. The amount of communication between the FDA that is relevant to the argument being made, for which there is no evidence for, boils down to these 13:49:32 interactions.

The bottom line is that these filters received substantial equivalence. They were cleared medical devices. There was no distinction whether they were pre-1976 or their predicates had been reclassified. Every single filter 13:49:50 received substantial equivalence. Not a single PMA.

Let me transition over to what Mr. North said about the fact that there were two situations. He cited the *Papike* case and the *Degelmann* case, as if they are the same. They are completely different. *Papike* dealt with a counterpart 13:50:09 regulation and an entire line of cases where claims, common

13:50:13 law state -- state law tort claims were preempted because there were counterpart regulations specific to a device promulgated by the FDA in a similar lawmaking progress that was described in *Riegel* and *Lohr*, and therefore those claims
13:50:29 were considered preempted.

Those are limited to warnings. There was warning language in those counterpart regulations. Completely different than in Bard's papers where they claim the separate situation of the *Degelmann* case, which is vacated and no
13:50:46 longer good law. If it were good law and I had to argue that the differences are, they are vast.

First of all, *Degelmann* was a false advertising case, an unfair competition and false advertising case. It did not deal with the design of the product at issue. *Degelmann*
13:51:02 actually says in order for the class to recover in this lawsuit, a court would have to hold that the California's UCL and false advertising law required something different than what the FDA required in order for the defendant to label the product as a disinfectant. There was an issue with the label
13:51:21 and what was represented in the label and were they representing the product accurately.

The contact lens guidance is comprehensive and detailed. And the *Degelmann* court also said in order for a contact lens care solution to be labeled as a contact lens
13:51:42 disinfecting solution, it should meet the primary performance

criteria of the stand-alone procedure for contact lenses in disinfecting products. Those were contained in the guidance document.

Primary performance criteria. These are criteria that no longer exist in the MDA. The contact lens guidance, as it compared to the IVC guidance, is unbelievably detailed. There are specific materials and testing agents, the specific test organisms, the testing and media, and it's specific as to which ones. They are labeled and documented.

Beyond the testing materials, a testing method is laid out, which does not occur in the IVC filter guidance. Culture maintenance. Preparation of microbial challenge. In other words, if you're disinfecting, how do you infect it first before you can disinfect it? It's five different bacteria and fungi that have been known for hundreds of years, and the testing laid out how to harvest the cultures, how to suspend the spores, how minutes to keep it there, the gravity at which to centrifuge it at, and how much to dilute it. And that's before you even get to the test procedure, which involves the preparation. I've only included three steps. There are seven. The preparation, the storage, the actual collection of samples before you test. It is laid out in this guidance document. And then, you get to the performance requirement.

Bard's IVC filter document contains no performance

13:53:14 standards. There are no specific federal requirements. *Riegel* tells us that a requirement is created by the PMA process. Federal requirements are -- are the things that are promulgated in a lawmaking process.

13:53:27 The IVC filter guidance, Mr. North covered aspects of things such as the sheath and things like that.

The scope, he -- although he did not point out, is that it -- it states that this draft guidance has been developed in an attempt to identify, an attempt to identify, 13:53:43 design considerations. There is nothing specific about it. It's a submitter's responsibility to conduct testing which adequately addresses the concerns outlined below, as well as any others which may arise due to the uniqueness of the design. It's the manufacturer that has to come up with the 13:54:01 performance standards. They're not federally imposed.

Labeling. There is nothing in the IVC filter labeling for IVC guidance that is specific. It just considers category, indications for use, contraindications, and warnings. This is not a federal requirement, as Mr. North 13:54:22 alleged. It has a section for indications for use. It has a section for contraindications, with one in particular.

And with regard to claims that have been made in this case, again, there are no design performance standards here, nothing about the design of a filter is addressed, much less 13:54:40 retrievable filter, because this guidance came out before

13:54:43 retrievable filters were even on the market.

And the only specific warnings, the only potential crossover, again, in the world if *Degelmann* were still good law, is that there is specific labeling language for MRI

13:54:57 compatibility. There is no labeling language here at all for any disease state or injury at issue in this case.

They are completely different.

Furthermore, guidance is not law.

The footnote actually says "this document is intended

13:55:14 to provide guidance. It represents the agency's current thinking. It does not create or confer any rights for or on any person, and does not operate to bind the FDA or the public. Alternatives approaches may be used if such approach satisfies the requirements of the applicable statute,

13:55:31 regulations, or both."

This is *Lohr*.

Statutes and regulation are general controls. *Riegel* tells us -- actually, *Lohr* told us and *Riegel* upheld it 15 years later, that the MDA does not require a device maker to

13:55:48 make a device that takes any particular form for any particular shape.

Guidance is not law, it's not a federal requirement. And according to *Lohr*, because the federal government did not weigh the competing interests relevant to the particular

13:55:59 requirement in question, reach an unambiguous conclusion about

13:56:03 how those competing considerations should be resolved in a particular case, or a set of cases, and implement that conclusion via specific mandate on manufacturers or producers.

The guidance document does not do that. It is not a 13:56:17 federal requirement. Special controls are not federal requirements. Special controls were mentioned in *Lohr*, and in the midst of the sweeping language the Supreme Court made, it did not say special controls were federal requirements. They were regulatory tools.

13:56:39 Your Honor, we saw this light earlier with regard to the difference between, or the alleged difference between reclassified devices and any impact that might make on this case. Again, this is of no particular moment.

This guidance also states -- I'm sorry, this 13:56:55 regulation also states that "any representation that creates an impression of official approval of the device because of complying with premarket notification regulations is misleading and constitutes misbranding."

Any representation.

13:57:14 Bard has made representations throughout their motion that they are something like PMA, they are akin to PMA, that they should enjoy the protections of the express preemption clause because what they went through and how unique their record is, they should be -- these claims should be preempted. 13:57:34 They are prohibited from doing that under the CFR.

13:57:41 This language that I just quoted was in every single substantial equivalence letter. They are prohibited. It's not a -- not often quoted or forgotten regulation. They saw it every single time they received substantial equivalence. 13:57:56 Yet they're making the representation that their application is something like PMA approval. That is the continental divide. You -- the FDA says each time they give you clearance for your device to get to market you cannot say in any way any representation that creates an impression that you are like 13:58:16 the PMA process.

Furthermore, if Bard wanted to enjoy the express preemption protections, they could have submitted a PMA application.

When we looked at the 807.87(l), which is the 13:58:37 regulation that allows for the commission -- for the FDA to ask for any additional information for a 510(k) application, they can submit the requested data, a new premarket notification, or submit a premarket approval application in accordance with Section 515 of the Act. If the additional 13:58:56 information is not submitted within 30 days, we covered that.

Bard had 33 opportunities to submit a premarket approval application each time they responded to the defendant -- I'm sorry, to the FDA's deficiency letters. They did not do so.

13:59:11 And their deficiencies went on and on. That is why

13:59:15 there are so many responses and that is why there are so many exhibits attached to their motion. This is, again, the blow by blow by blow rendition of what their product went through.

Your Honor, defendants' motion should be denied for
13:59:29 the initial statements I made at the outset of my argument. There is absolutely no evidence in the record of what they're claiming. They have not properly applied the express preemption test. And they have engaged in improper burden shifting, asking plaintiffs to provide what they have not in
13:59:45 the record.

THE COURT: All right. Thank you.

Mr. North, I'll give you about five minutes to reply, but then I want you to address Booker.

As I understand or my review of the motion shows that
14:00:04 the manufacturing defect claims of Ms. Booker, which are in Counts 1 and 5, have been withdrawn. The failure to recall or retrofit in Count 6 has been withdrawn. Breach of warranty claims in Counts 10 and 11 have been withdrawn. Bard is not moving for summary judgment on the design defect claims in
14:00:28 Counts 3 and 4.

And so the only things we need to address are the failure-to-warn claims in Counts 2 and 7, the misrepresentation claims in Counts 8 and 12, the negligent per se -- negligence per se claims in Count 9, and punitive
14:00:51 damages.

14:00:56 MS. HELM: That's correct, Your Honor.

THE COURT: So it seems to me we can maybe take 10 or 15 minutes for that argument since it is a more discrete group.

14:01:02 Mr. North, why don't you go ahead and give the reply you would like to on the preemption motion.

MR. NORTH: Sure, Your Honor, and I will be brief.

I just wanted to point out three things. Revisiting the Court's question about Justice O'Connor's dissent in *Lohr*,

14:01:15 I do note that she says that the 510(k) process standing alone does not indicate -- have a preemptive effect, but she goes on to find that other claims are preempted because of specific standards that she thought should apply.

So we're not arguing here that just the general

14:01:35 510(k) process by itself results in preemption, but the application of the specific standards in this case, the guidance as applied by the FDA over the 15 years. And that same point, I think, is relevant to all of the cases cited by the plaintiffs.

14:01:54 These were cases where a manufacturer came in and argued the SDMA, the 1990 revision, a modification of the Act, somehow rendered *Lohr* incorrect.

We're not saying that that alone, the enactment of the SDMA, somehow justifies preemption. We're saying that's a

14:02:19 factor, but what we are pointing to is the specific record we

have in this case with a specific standard, the FDA guidance for IVC filters, and how the agency has applied that. And in none of those cases is there that sort of circumstance.

And lastly, Your Honor, with regard to the standard, the FDA guidance, I would note that the plaintiffs say this is not a performance standard. Well, it has a lengthy section on filter performance. It addresses many different aspects of filter performance. It gives the manufacturer very specific instructions as to how these performance attributes should be evaluated.

And then it also -- and this is the next page -- under that general heading of filter performance, it lists the ones I mentioned earlier: Simulated deployment, introducer sheath suitability, a test regarding clot trapping ability.

It says "this test should demonstrate that the device can capture clinically significant emboli yet still permit sufficient blood flow." It is a performance test that is being required.

The same thing with regard to filter fracture, caval perforation, Thrombogenicity.

In short, this FDA guidance is a performance standard, and it's very specific to filters. And it's not just aspirational, Your Honor. The record in this case makes it clear that if we had not complied with that -- and even when we did, the FDA wanted more and more data. It's not just

14:04:04 deficiencies. We presented tests in our original submissions that fulfilled each and every one of these criteria. But they wanted additional information because they were assessing the safety and effectiveness of this device.

14:04:18 So this is, we submit, one of those rare instances of something more or something like it, as Justice Gorsuch mentioned in *Caplinger*. It may not be a PMA review, but it is certainly something like it. And because of the application of this specific standard, we would ask that the Court grant

14:04:37 this motion.

Thank you.

THE COURT: Okay. Thanks, Mr. North.

MS. HELM: Good afternoon, Your Honor. I'm Elizabeth Helm.

14:04:52 And you are correct that we are down to just a few issues on the motion for partial summary judgment: The misrepresentation claim, the negligence per se claim, the failure-to-warn claim, and punitive damages. And I'm going to address them in that order.

14:05:07 The misrepresentation claim fails as a matter of law. This is basically a no-evidence motion. Under Georgia law, reliance is a necessary element, whether it's negligent misrepresentation or fraudulent misrepresentation.

Ms. Booker -- and the case cite for that is *Potts*

14:05:25 *versus UAO Georgia Agricultural Chemical Company*, the Georgia

Court of Appeals case from 2002.

Ms. Booker's testimony is she didn't even know she had a Bard filter until after her -- until her lawyer told her after she filed suit, or contacted her lawyer. She received no information from Bard. She never had any communications with Bard.

As to Dr. D'Ayala, the implanting physician, his testimony was that he did not rely on any information from Bard, and he specifically did not recall any conversations with the Bard sales representative, who would have been his only source of communication with Bard.

So as a matter of law they have failed to establish that crucial element of any reliance for misrepresentation.

As far as plaintiffs' negligence per se claim --

THE COURT: Before you leave misrepresentation, the argument you just described was the second argument in your brief. The first one was that misrepresentation doesn't exist under Georgia law in a product liability case. Are you no longer asserting that argument?

MS. HELM: Your Honor, actually, in the interest of brevity, whether it exists separately or as an element of product liability, reliance is a necessary element, and they can't meet that either way.

THE COURT: Well, but so are you still arguing there are no misrepresentation claims for product liability that are

distinct from failure-to-warn claims?

MS. HELM: No, Your Honor.

THE COURT: You are not making that argument?

MS. HELM: No, Your Honor.

THE COURT: Okay.

MS. HELM: As to their negligence per se claim, Your Honor, the official code of Georgia Annotated 51-1-6 codifies negligence per se, but it requires as a prerequisite an underlying statute or law that gives a private cause of action.

The plaintiffs concede that their negligence per se claim is based on the Federal Drug and Cosmetic Act, which the United States Supreme Court has said in *Buckman*, at 531 U.S. 341, does not give a private cause of action. So as a matter of law they don't have a negligence per se claim under Georgia law because it requires an underlying law or statute that gives a private cause of action. They have a negligent design claim. It's just not as a violation of a statute because they concede in their response that the only thing they're rely on is a violation of the FCDA -- excuse me, FDCA. So they don't have an underlying statute that gives a private cause of action. As a result, under Georgia law and under 51-1-6, they don't have a negligence per se claim.

It does not create a separate cause of action, 51-1-6. It simply codifies the concept of negligence per se

14:08:34 in Georgia.

Your Honor, that brings to us the failure-to-warn claim. And both parties spent a tremendous amount of time in our briefs addressing this issue of rates and comparative 14:08:50 rates of filters. And I want to back up. And the important time period here is June 21, 2007, when Ms. Booker was implanted with her G2 filter.

Under Georgia law, to prove -- to survive summary judgment on a negligent to warn claim, the plaintiffs have to 14:09:10 prove a duty, breach, and proximate cause. Basically the three elements of negligence.

In this case, I think we all agree that the duty was to the learned intermediary, Dr. D'Ayala, who implanted the filter.

14:09:26 If you reed Dr. D'Ayala's testimony in his deposition, he was a true learned intermediary. He was well versed on filters, he was well educated on filters. He testified unequivocally that he was aware of the risks of filters at the time he implanted Ms. Booker's filter on June 21, 2007.

He also testified unequivocally that he made a risk/benefit analysis, that she needed a filter, he decided to use a G2 filter, and he communicated to her through the informed consent process the risks associated.

14:10:06 He also admitted he was aware of the very risks, the

very complications that resulted -- Ms. Booker ultimately experienced with her G2 filter.

Bard met its duty. It provided information to Dr. D'Ayala. He admitted he had access to the IFU, which included the risks at issues, the complications that Ms. Booker experienced.

He also admitted that he relied on information from the -- from his colleagues, from the FDA, and from his experience, and he had all of that in 2007, when he implanted Ms. Booker's filter.

This question of rates, we argue that the plaintiffs are trying to create a new duty. A duty to warn of rates. Plaintiffs argue no, it's not a duty, it goes to the adequacy of the warning.

But based on the record in this case, while we disagree rates should be a part of a warning, and I'll be happy to address that, based on the record in this case, the third element, whether it's a duty or it goes to the adequacy of the warning, the plaintiffs cannot meet that third element of proximate cause because under George law, the plaintiffs have to show that but for the inadequate warning or but for the missing information, the doctor would have changed his prescribing habit.

In other words, they have to show that had Dr. D'Ayala had the information they claim he should have had,

14:11:47 he would not have implanted Ms. Booker with a G2 filter.

Dr. D'Ayala testified to the contrary. His testimony is -- when asked, after being provided with some internal Bard documents relating not to the G2 filter but to the Recovery 14:12:06 filter, "After seeing this information would that have been enough for you to use another filter?"

His answer is, "Difficult to say with certainty. It would depend upon what other filters we had and what their problems would have been."

14:12:28 In another question he was asked, "If there was a 25 percent risk of filter fracture, can we safely say you would not have used that filter?"

And his answer is, "Most likely. But you have to understand that you have to have a way of treating these 14:12:50 difficult patients. Some filter has to be used and it becomes a matter of deciding which filter is best, so to speak. And sometimes that's not entirely clear."

Nowhere in his testimony, after being provided with hypotheticals, after being provided with internal documents 14:13:11 about the Recovery filter, after being provided with articles that were written three years after Ms. Booker's filter was implanted, nowhere in his testimony does Dr. D'Ayala say "I would not have used a G2 filter even knowing all of that information today." He doesn't say it.

14:13:32 As a matter of law they can't establish that

14:13:36 proximate cause that is necessary under Georgia law to survive summary judgment on a failure-to-warn claim.

Plaintiffs rely on two other cases involving Bard, *Cisson versus Bard*, which was women's health mesh case, and 14:13:52 *Cason versus Bard*, which was a filter case decided in Georgia. Both of those are factually distinguishable from this case.

Summary judgment is based on the facts of this case. It's not based on *Cisson*, not based on the facts of *Cisson*. It's not based on the facts of *Cason*. In both of those cases, 14:14:14 the doctor testified completely differently than what Dr. D'Ayala said. In both of those cases, the doctor testified that he would have made a different prescribing decision based on the information provided to him during his deposition or trial testimony.

14:14:33 So while -- while there's a debate and, respectfully, we do not believe rates should be considered as part of either the duty to warn or as part of the adequacy of the warning for a number of reasons. And, frankly, both the FDA and plaintiffs' experts agree with us. Plaintiffs' regulatory 14:14:55 expert has testified you cannot use rates for comparison. You can't compare apples and oranges. The FDA has said you can't use the MAUDE data for rates purposes.

So it should not be a part of the warning, it should not be a part of the duty. Neither of the courts, neither 14:15:13 *Cisson* nor *Cason* said it's part of the duty. They both

addressed it in the proximate cause prong of the duty to warn. They both addressed it saying the doctor would have made a different decision based on the information.

Your Honor, because they can't meet proximate cause, it's an "and" standard. It's duty, breach, and proximate cause. Because as a matter of law, based on Dr. D'Ayala's testimony, they can't meet the proximate cause prong, their failure-to-warn claim fails as a matter of law.

And then finally, Your Honor, their punitive damages claim also fails as a matter of law. It's again based on rates, and if you look at their brief they spend pages outlining information. And if you look -- you don't even have to look carefully, but if you look at their bullet points it says, Recovery filter, Recovery filter, Recovery filter, Recovery filter. And then there's a couple of bullet points where they conflate the Recovery and the G2. But their punitive damages claim is, again, based on rates and problems they contend existed in the Recovery filter, not in the G2 filter.

And their punitive damages claim is based on the Georgia statute that uses this language, "conscious indifference." And the *Cisson* court actually addressed this question of conscious indifference and said "to have conscious indifference, you have to find, the Court has to find, that the defendant was aware of the danger, failed to warn of the

danger, and took no action to remedy the danger."

In other words, the *Cisson* court said that the defendant did nothing.

In this case, the plaintiffs admit that the G2 filter that was implanted in Ms. Booker is actually a redesign of the Recovery filter on which they base their punitive damages claim.

They also admit that the IFU that was with the G2 filter contained warnings of the very complications that Ms. Booker experienced in this case. So their conscious indifference, their failure -- their Bard did nothing, fails.

They admit Bard warned. They admit the language was in the warning. They admit Dr. D'Ayala was warned. They admit that Bard actually did something. The G2 design itself was -- addressed all of those bullet points on the pages of their brief.

Then they go forward and say, Well, wait, wait. Bard made design changes in the future. So they were consciously indifferent in 2007 because they continued to evaluate their product and made subsequent design changes in the future. That is not a basis for punitive damages. You can't impugn future knowledge back to 2007 at the time Ms. Booker's filter was implanted.

Your Honor, their design claim, we agree, is probably a question of fact. We didn't move on design. But the four

14:18:35 remaining claims that we moved on -- negligent misrepresentation, negligence per se, failure to warn, and punitive damages -- we believe fail as a matter of law, and we'd ask the Court to grant the motion.

14:18:47 THE COURT: All right. Thank you.

MR. O'CONNOR: Your Honor, just one moment. I just need to get set up here.

Your Honor, I'm going to start with the failure to warn, if that's okay with you. And as I get into that

14:20:08 argument, I think one of the most important aspects of the learned intermediary doctrine is the importance that it accords the patient/physician relationship, that the -- one of the most important communications that can occur between a doctor and the patient has to do with risk and benefits. And

14:20:35 that's why it becomes even more critical that when a doctor goes through the risk/benefit analysis that he has the best, the most updated, the most recent information on risk associated with the device that he's going to use. And if there are increased risks, then they need to be communicated

14:21:08 to that doctor.

There's a lot more to a warning than just an IFU. Labeling encompasses everything that a manufacturer says about a filter or a product. Whether it's touting it, it should be also talking about information that it knows that a doctor

14:21:28 needs, critical information, to make that very important

analysis in meeting with a patient.

And as we were talking today -- and I just want to make sure I can get this up --

MS. REED ZAIC: Show you the trick. Stand here and go forward with this. Point behind you.

MR. O'CONNOR: Going through what was filed here. The argument that was made today is identical to an argument that was made in Georgia, before a Georgia judge applying Georgia law. And Pamela Cason, like Sherry Booker, was another patient who received the G2 filter. Like Sherry Booker, her filter failed and fractured and migrated. And that's what happened to Sherry Booker.

And -- and the information in the IFU, while it does cover those risks, what the court in *Cason* found is that -- rejected the argument that was made then, rejected the argument that was made here, that there was a genuine issue whether the warnings provided by Bard were adequate.

Reviewing their argument about the IFU. There, the judge in *Cason* found that there was evidence that the G2 filter had a significantly greater propensity to fracture, migrate, and perforate the IVC other than IVC filters. And given this evidence combined with the evidence that the defendants did not warn Ms. Cason's doctor about the increased risk associated with the G2 filter, a reasonable fact finder could conclude that the IFU did not contain an adequate

14:23:49 warning regarding the G2 failure.

THE COURT: I have read the *Cason* case.

MR. O'CONNOR: And there they made the same arguments that they've made here.

14:24:00 Your Honor, when I was looking at other cases that they were citing, and I looked at the *Wyeth* case and the *Ellis* case, and *Wyeth*, that had to deal with a diet drug. *Ellis* had to do with a pain pump. But the common theme in that case was the use by those manufacturers of their sales force. How

14:24:25 important the sales force was to communicate the risks, the complications, to continually warn the medical staff about problems associated with third-party activation, to continually update doctors about complications that were being found about the particular diet drug in *Wyeth*.

14:24:47 And here, Bard really hasn't cited anything from their sales force. But we have. And we cited testimony from Robert Cortelezzi, testimony from Jack Sullivan, testimony from Dan Orms, testimony from Dan Fischer -- excuse me, Tim Fischer. Testimony from Robert Ferrara, the sales rep in

14:25:14 this case.

With respect to the first sale -- regional sales managers, what they acknowledged is that relationship with the doctor is important, it's based on trust, and they know that doctors rely upon them. Rely heavily on them to provide them

14:25:33 with updated, accurate information. As a matter of fact, Bard

recognized that that was a very effective means to communicate information to doctors. And despite the evidence that we've shown here that was shown in the *Cason* case, that Bard was well aware of increased rates of failures in its G2 filter, that it was not resistant to migration, that it was not as resistant to fracture, none of that information was given to the sales force. And it became a very effective way to keep the doctors in the dark.

And that's what happened in this case. Because as you can see from the record we provided, Dr. D'Ayala testified he would have liked to have known about increased complication rates. He would have found important information contained in health hazard evaluations. But he wasn't given that information.

And when you look at the informed consent process, it really is an objective process. And -- and -- and even Dr. Grassi, an expert of the defendants, testified, and we gave that you testimony, that the issue is what would a reasonable patient want to know? And along those lines, asking a doctor today questions about what he would have wanted to know then is one piece of it.

And Dr. D'Ayala's testimony definitely creates a question for this jury who's going to hear this case to hear and review.

And right now, as we sit here, we come to you, we're

14:27:29 entitled to every reasonable inference in our favor. But as you saw, Dr. D'Ayala said that there was important information, it would have affected his decisions, but it gets to be more than that.

14:27:44 Chris Ganser, the vice president of regulatory affairs, provided testimony that, yes, doctors would want information about failure rates. Yes, doctors would want information about test results. Yes, doctors would want to know if Bard was aware that its filter wasn't, in fact, 14:28:08 bringing strength and stability to a new level, but was having increased rates of failure in terms of fracture, migration, penetration, which was the case here.

And in December of 2005, it's no wonder that the medical director in this case, Dr. Ciavarella, asked the 14:28:30 question knowing that there was so many increased rates of failures with the G2, knowing that they were marketing and implanting these filters and that they were being held out as permanent filters, knowing that the G2 was not behaving at all like a permanent filter because they had one, the 14:28:53 Simon Nitinol, he asked the question, why shouldn't doctors be using the Simon Nitinol filter which literally has no complaints.

So when we look here at the learned intermediary doctrine, and we look at what Bard was well aware of, and -- 14:29:20 and considering the evidence here that is even more developed

than in the *Cason* case of the knowledge this company had, Bard had, of the G2 -- which, by the way, the predicate device for the G2 was the Recovery. And as a matter of fact -- let me find my note -- when the G2 first came out, they were calling it the Recovery G2.

These filters were all in the same family. And the G2 wasn't behaving any better than its relative, the Recovery. In fact, it was behaving worse in terms of things like [[caudal migration. And Bard knew that. And that's information that doctors not only would have wanted to know, it's information that doctors had to know. Because when everybody wants to talk about risk and benefit and a doctor needs to make that important decision and then have that ever important conversation with his patient, he needs to know what are the risks. And if there is an increased risk that the company Bard is aware of, he is not only entitled to know that, but he has an absolute right to know that. Because Bard had all sorts of effective measures to communicate this information.

And like what happened to Mrs. Cason, the same thing happened to Sherry Booker. And just like there was a question of fact whether that warning was adequate based upon what Bard knew and didn't disclose in any form, much less the IFU, about the increased risk of the G2 filters, that is a question that this jury should resolve.

14:31:42 And if you look at the evidence and you look at Dr. D'Ayala's testimony, and you consider the testimony of experts in this case, including Dr. Kinney and Dr. Roberts, who talked about why it's important for doctors to know about 14:32:00 increased risk, if you look at testimony from their own expert, Dr. Moritz, who agreed that Bard's internal information is information he would have wanted to know in making those decisions, then certainly that is an issue that reasonable minds should consider, and certainly reasonable 14:32:25 minds can certainly have different -- different views on that.

So we believe we have established questions of fact on both the inadequacy of the warnings, the complete failure of Bard to keep the medical community apprised of the increased failure rates of these filters, beginning with the 14:32:54 Recovery and then going into the G2, and how those filters compared worse than the Simon Nitinol and even with other filters. Bard had that information and they had that information in their possession.

Now, on this issue of expert testimony, I can 14:33:13 supply --

THE COURT: We're at about 15 minutes, Mr. O'Connor.

MR. O'CONNOR: Pardon me?

THE COURT: We're at about 15 minutes on your --

MR. O'CONNOR: Let me just get to the next issue, 14:33:22 Your Honor.

14:33:22 If negligent misrepresentation is encompassed by failure to warn, that just goes to the point that the doctor is the party that needs to have the accurate and truthful information. And if that's not getting to the doctor, then 14:33:40 those claims should go to toward forward to the jury.

On the issue of negligence per se, Your Honor, when we were doing research we found a case from the Ninth Circuit, and it is *McClellan Versus I-Flow Corporation*, 776 F.3d 1035. I have a copy if you would like it.

14:34:03 THE COURT: Actually, we've seen that case.

MR. O'CONNOR: Pardon me?

THE COURT: We found that case.

MR. O'CONNOR: You have the case?

THE COURT: Yeah.

14:34:10 MR. O'CONNOR: Well, Your Honor, that case basically in the Ninth Circuit said that the court in that case should have instructed the jury with negligence per se that relied upon FDA regulations. And it noted that *Buckman* really wasn't applicable because *Buckman* concerned claims of fraud on the 14:34:33 FDA, and the reason why that claim couldn't go forward is because the recognition by the court said the FDA is equipped to police its system for fraud.

But in terms of allowing a negligent per se case to go forward, *McClellan* in 2015 found that it certainly should 14:34:57 go forward.

14:34:59 Finally, Your Honor, in terms of punitive damages, we have provided replete record of evidence that shows a complete conscious want of care by Bard stemming from the failures to disclose the known increased complications of its filters, 14:35:20 ignoring suggestions by independent doctors that the filter should be redesigned. Even its own engineering staff.

Bard was in a race to a market. The optional filter was a great idea; it meant major profit. And they did that at the expense of safety. And the evidence in this case shows 14:35:46 clearly and convincingly that what Bard knew about its filters was not good, and that what Bard did, rather than taking them off the market, rather than holding off on sales for a while, it continued to tout them as bringing strength and stability to a new level, and it worked in a very strategic way to keep 14:36:18 the medical community in the dark by keeping their own sales force in the dark.

As a matter of fact, even in the cases we've gone through discovery and deposed experts, we find they're not even giving their experts the internal information that they 14:36:31 have been well aware of.

So once again, Your Honor, I think -- I'm sure my time is up now and I'm willing to sit down, but here we are responding to this motion for summary judgment, and as the plaintiffs in this case we must receive every reasonable 14:36:51 inference in our favor. And what the evidence shows is that

Bard, the warnings that were given doctors, were entirely inadequate, they did not talk about what Bard knew about increased failure rates, and that in terms of punitive damages that Bard was keeping information away from the medical community and consequently the patients.

And there was evidence that that was a conscious want of care, a conscious and deliberate indifference to not only the rights of doctors and patients, most importantly, but also to their safety, and that's what it case is about.

THE COURT: Okay. Thank you.

Any brief comments?

MS. HELM: Very brief, Your Honor.

Your Honor, on the failure-to-warn claim, plaintiffs rely on *Cason* very heavily and make the argument that the identical argument was made to a judge in Georgia. What's different about *Cason* is the record. The record in Booker is different than the record in *Cason*. And, respectfully, this Court has to decide the failure-to-warn claim on the record in Booker, not the record in *Cason*.

And if you look at -- we submitted Dr. D'Ayala's entire deposition. It's not incredibly long. But the entire deposition is before the Court, and I think if you read his entire deposition you will not find anywhere in there where he says "I would not have used the G2 filter." Knowing all of this information that the plaintiffs put in front of him

during the deposition about the Recovery filter, about rates, about articles, after being told all of that, he never said "I wouldn't have used it." He said that might have been important information, but he never said he wouldn't have used the G2 filter.

The other thing --

THE COURT: Let me ask you a question on that, if I can.

My only citation here is to, I think, a statement of facts, if that's the document at 8169. It's paragraph 333. It's a quote from Dr. D'Ayala's testimony, where he says, "The answer would have to be yes...I would have used a different filter if there was a different filter that I knew of that was better, in terms of its safety profile."

What is your -- I don't know if you can find that.

MS. HELM: I --

THE COURT: I don't have a deposition page cite. Check pages 32 and 33 of your deposition, see if that's where it is.

MS. HELM: I have the statement of facts, Your Honor.

THE COURT: It was pointed out I said 333. It's paragraph 338.

MS. HELM: If the Court will indulge me, Your Honor, I'll find it.

Your Honor, the testimony -- I found it. It's

14:40:58 actually his deposition testimony on pages 62 and 63.

THE COURT: Can you read the question and answer there. I've only got the excerpt in my notes in front of me. I don't have the actual exhibit.

14:41:20 MS. HELM: Your Honor, the question and answer is very long. I'll be happy to read it.

THE COURT: Well, there's a place where he begins in the answer "With regards to the Bard filter would I have used a different device if I knew at the time that the Bard filter

14:41:35 was not ideal or as good as some of the other implants? The answer would have to be yes."

MS. HELM: That is the answer -- that is the last sentence of a page-and-a-half answer.

And the answer -- they're talking about a clinical

14:41:53 trial and he says the trial is a great study and it's very interesting but there are problems with the study, as there are problems with every study, and the fundamental problem you have with this trial is that it's randomized. Patients who were candidates for caval interruption are not -- in other

14:42:12 words -- I mean, he goes on and on and on. Says Ms. Booker needed a filter.

You have to back way up and -- I apologize. You have to back way up to get into the question of if you had known fracture rates from this study would you have used a different

14:42:35 filter, and he does give the answer that you read.

14:42:37 He then gets asked the next question if it -- now that you've seen these documents and it had -- would you have not used a Bard filter. All of these documents collectively. And that's on that same page, on page 63 he says, "It's 14:42:54 difficult to say with certainty. It would depend on what other filters we had at the time and what their problems would have been."

And then he goes on later to say, "I can't say."

So -- and under *Watkins versus Eli Lilly*, which is a 14:43:14 Northern District of Georgia case from 2012, the court held you can't speculate, you have to -- the plaintiff has to show that the doctor would have changed his prescribing habits, would have used a different product, and Dr. D'Ayala simply didn't say it.

14:43:33 He -- Your Honor, he was actually truly a true learned intermediary. He was very smart, he was very well versed on filters. And a complete reading of his deposition, he told us what he relied on and what he knew.

He admitted he was aware of the risks in 2007 when he 14:43:52 implanted the filter, and that he addressed those risks with Ms. Booker. He also admitted that he never relied on and never requested information, internal information, from a company. And when asked about a specific document, he gave a great answer --

14:44:11 THE COURT: I'll read the whole deposition.

14:44:13 MS. HELM: I think you should, Your Honor, because I believe the record is very different from *Cason*.

And I want to point out one more thing in *Cason*, and that is Judge Shoob never addressed whether comparative rates 14:44:26 are part of the duty or part of the adequacy of the warning. Judge Shoob went right to proximate cause. And I think that he said "based on this record I find a question of fact."

Frankly, that's what happened in *Cisson* too. *And Cisson* was a posttrial motion, it was not a motion for summary 14:44:45 judgment.

The other difference between *Cason* and this case is there was expert testimony in *Cason* relating to the use of rates. In this case, the experts, plaintiffs' own experts, Dr. Parisian says you can't do what the plaintiffs are asking 14:45:01 you to say that Bard had an obligation to do. She says you can't use comparative rates.

The FDA says, and it's cited in our brief, you can't use the MAUDE database for comparative rates.

So that's a difference in the record in *Cisson* than 14:45:24 the record before this Court.

And then finally, Your Honor, as to punitive damages, Mr. O'Connor based his entire punitive damage argument on two things: One, the Recovery filter, and there's been no showing that it's substantially similar. It should be considered for 14:45:39 punitive damages. And, frankly, we think that's a significant

14:45:42 issue that will likely get briefed at length in this case.

And the second is on the fact that Bard --

THE COURT: Wait a minute. Get briefed when at length?

14:45:52 MS. HELM: Your Honor, to the extent that you're going to rely on the Recovery filter for making a decision on punitive damages, we would ask you to hold off until we have an opportunity to brief in a motion in limine, explain why the Recovery filter is not a substantially similar to it filter to 14:46:09 the G2.

THE COURT: But you argued that in these briefs; right?

MS. HELM: We argued that it was not, yes, Your Honor. We did. That's fair.

14:46:16 The other argument he made today is that we -- the plaintiff's entitled to punitive damages because Bard did not take the product off the market. Well, they've withdrawn that claim. They withdrew their failure-to-recall claim, and that's how Bard would take it off the market. And so the 14:46:33 basis of their punitive damages, again, is based on the claim.

And then finally, Your Honor, in the Jones case and the records before the case, we cited a long list of cases outside of Georgia because Georgia -- there's -- about the rates issue, and I just wanted to make sure the Court was 14:46:51 aware of those.

14:46:52 THE COURT: I have looked at the long footnote and the cases in the text that you cite, so I know what those are. And I've read about half of them so far.

MS. HELM: Thank you, Your Honor.

14:47:01 THE COURT: Okay. We're going to take a break for 15 minutes for the benefit of the court reporter. We'll resume at 3 p.m. And we'll then talk about case management matters.

(Recess taken from 2:47 to 3:01.)

THE COURT: Thank you. Please be seated.

15:02:21 All right. Counsel, I'd like to talk to you about the case management issues that were raised in your joint status report. One of the issues that I think we need to address is the order in which I should continue working on the filed motions. We've got a hearing on December 15th. I am

15:02:43 confident I will not be able to finish the four motions planned for today plus the five or six that were scheduled for December 15th by the 15th.

We have left in the motions that were set for today the two disqualification motions with respect to experts, and

15:03:08 then the motion on David Kessler and Suzanne Parisian. Those were also set for today.

I guess the question is do you want me to turn to those next for December 15th, or is there some reason you think it would be better for me to jump to the list of motions

15:03:31 that were set for December 15th?

15:03:36 MR. LOPEZ: From the plaintiffs' perspective, Your Honor, I think we ought to keep this order. We kind of negotiated this order; it seems to make sense for both sides.

THE COURT: Okay.

15:03:45 MR. LOPEZ: So we'd like to keep that order.

MR. LERNER: We agree, Your Honor.

THE COURT: So what we'll do is we will work on those four, and we will aspire to work on the first two in the December 15th list, which are the opinions of Kinney, Roberts, and Kalva, and then the opinion of Muehrcke, M-U-E-H-R-C-K-E.

15:04:02 MS. REED ZAIC: Muehrcke, Your Honor.

THE COURT: I don't know if we'll get to those, but what I'll try to do is let you know a week or so ahead of time how we're doing so you know what we're going to argue on the 15th.

15:04:26 But a bigger question, obviously, that this presents is I'm just not going to be able to get all of the issues, all of the motions on this list, decided by the January 19th or as of the January 19th argument that we had talked about. It's just not going to be physically possible for me.

15:04:44 So a second question I have for you is whether you think all of the issues on the list now for those hearings need to be decided before the Booker bellwether trial, assuming I don't -- well, Booker's going in part in any event on design defect, even if I grant other parts of the motion.

15:05:02

15:05:10 So the question is do we need to get all of those motions resolved in order to do the first bellwether trial, or are there some that don't apply to the Booker case that we could hold off on so we can still try to get everything done 15:05:22 we need to before the Booker trial?

MR. LOPEZ: Well, sadly, probably most of them, Judge. I can see maybe two or three we might reserve, I'm not sure how much that will help.

THE COURT: Well, anything helps. What are the two 15:05:58 or three you think would not need to be resolved before Booker?

MR. LOPEZ: There's a couple of -- I don't want to say quite yet, but I think one of them would certainly be, and then maybe one we think December 15th, whether or not both 15:06:12 Dr. Kessler and Dr. Parisian will be testifying in the Booker case. So we can probably make that decision certainly by next week.

And then we want to use one of the Doctors Kinney, Roberts, and Kalva report because it's relied upon by so many 15:06:40 of our other experts. So we want that resolved.

And then you would probably want us to choose which one of those doctors would testify in the Booker case, and we can probably make that decision.

THE COURT: Well, why don't I do this: I'm going to 15:06:54 plan to keep going down the list in the way you all presented

15:06:57 it to me. If you decide there are experts on this list that won't be needed for Booker, let me know and I'll jump over those motions as we move forward. That will save us some time.

15:07:08 We still, though, even if we knock out two or three of them, are not going to get everything decided as of the January 19th oral argument. And we've got a month, we've got February in there, before we get to the March trial date for Booker.

15:07:24 That leads to a second question which I have, and that is how many motions in limine do you all anticipate filing before a trial like the Booker case?

I will tell you that another fact is I typically limit parties to three-page motions in limine. I want it to

15:07:46 just cut right to the very heart of the issue so we don't have 15, 20 page motions in limine. If it's a *Daubert* motion, obviously I don't hold folks to that limit, but we've got the *Daubert* motions briefed. Now, if there is an unusual motion that can't be done in that amount of space, I'll certainly

15:08:04 consider that. But I try to really focus them and target them.

But still, if you're going to file 10 motions in limine, that's one thing; if you're going to file 30, it's a different thing. I need to factor that in in trying to get

15:08:17 ready for the trial in March.

15:08:23 MS. REED ZAIC: Let me take a stab at it, Your Honor.

Just in preparation for Austin trial, the case in Florida that was about to go and didn't, plaintiffs only filed four motions in limine. Now, that was also the product of

15:08:35 nego- -- pre-negotiation before the filing date of things we were able to work out.

In Mrs. Booker's case there might be some specific ones we would move on, that we would first negotiate with the defendants to see if we need to move at all, or we can reach

15:08:48 an agreement via stipulation that certain evidence wouldn't be presented at the time of trial.

So to make an estimate, I would say, and this is very rough, maybe six, five or six or --

THE COURT: I won't hold you to it. I'm just trying

15:09:04 to get --

MS. REED ZAIC: Right. Again, it all depends on the negotiations we engage in.

MR. LERNER: Your Honor, I would estimate about eight to 10.

15:09:13 THE COURT: Could you pull the mic over.

MR. LERNER: I estimate eight to 10 motions in limine.

THE COURT: And that's after discussions with plaintiffs you think there will be that many left?

15:09:22 MR. LERNER: I believe so.

15:09:26 THE COURT: I'll tell one other thing. My view is that motions in limine should not be used to pre-try the case. So if a motion in limine can be stated as an objection at trial that I can rule on, typically it ought not be a motion 15:09:38 in limine, unless it's truly unduly prejudicial. Motions in limine, in my view, instead should be used for evidentiary issues that will assist you in preparing the case, that may deal with categories of evidence. So keep that in mind.

But it sounds like we may have 10 to 15, or maybe 15:10:01 even a few more, motions in limine to resolve.

What do you think about the three-page limit? Do the kinds of motions you're thinking of lend themselves to that sort of targeted briefing?

MR. LOPEZ: I can think of one exception right now, 15:10:15 and that would be the *Cisson* motion.

THE COURT: That's the one you mentioned in the footnote --

MR. LOPEZ: Right. There's like three cases. It's basically our motion to exclude 510(k) and FDA process 15:10:29 evidence.

THE COURT: Okay.

MR. LOPEZ: That's going to need more than three pages, I'm afraid.

MR. LERNER: Your Honor, I think three-page limit 15:10:37 would be fine as well. I think there might be one motion that

we file that we might ask for additional pages.

THE COURT: What would that be for?

MR. LERNER: A motion in limine related to the Recovery filter. Evidence of migration and things like that.

THE COURT: Okay. We're going to come back and talk about these again, but let me ask the next question. I was surprised when I read the joint report and there was a suggestion made that the Booker case may settle between now and trial. I guess I had assumed that we'd pick the bellwethers to try them and weren't going to be doing settlement negotiations on a case-by-case basis between now and trial, so I had never factored in the thought we may lose a bellwether trial on the eve of the March trial date.

MR. LOPEZ: Well, the best way for me to address that is to discuss what has happened historically in these cases over the last six years, and that is both sides get geared up for trial and they don't settle until they get to the courthouse steps. Or until you're in trial.

So we had this case in March that got continued, the judge there had another calendar, he had to take another case. We were pretty -- we were pretty much -- we were inching together. We were getting closer in our negotiations in that case and, of course, as soon as the case got kicked, there's no more discussion from Bard about their interest in settling that case.

But I think the best way to respond to that, Judge, is this: I could just tell you based on history, we can't tell our client not to -- once we get to a certain level of negotiations -- the lawyers want to try the case. We just -- we think it's important to try the case, get the evidence in front of Your Honor and a jury, and whatever the verdict is, it is, because it will instruct everyone as to where this case might be going.

But I think the reason we suggested that is because historically that happens. I mean, the cases could settle as you get to trial.

THE COURT: But does it happen on bellwether cases? I mean, are you talking settlement on an individual bellwether basis?

MR. LOPEZ: No. My point to you is this: We never do. There's never an interest in settling these cases until we get well in- -- either at trial or well into trial when all of a sudden things change.

I can't -- I can't predict what's going to happen in this case other than the fact that I know historically what's happened in the past is that the settlement posture -- and I'm just going to say it, on Bard changes. Not the plaintiffs.

THE COURT: Well, but if -- if Bard were to come in on the eve of one of your stronger bellwether cases and make an offer your client couldn't resist, doesn't that distort the

whole bellwether process? I mean, what's the point of carefully picking these bellwether cases if one side or the other is going to try to pick off a few of them individually through settlement? Then we skew everything we tried to achieve by carefully selecting these five cases. And if we're going to do, I may as well just remand all the cases and send them back to state court, because there is no point in a bellwether process designed to get a representative look at how the cases play in front of a jury.

MR. LOPEZ: Your Honor, we have representative cases that have been either in trial, close to trial, courthouse steps. There are no secrets in this case. They know how we're going to try this case; we know how they're going to defend it. There have been values set on cases very similar to what Mrs. Booker's case is about.

Again, I agree with you. I think the bellwether process should work to determine what the risks are to both sides and how cases should settle. We want the Booker case to go to verdict. But we also understand -- there's been no offer. I don't want to you think we're negotiating. And it could be there is no offer. But I just think based on historical data that as we get involved in that case, that could happen. And that's why I think it's important, and this is not unusual in an MDL or in a mass tort where you have other -- some plaintiffs are more resistant and more resilient

15:15:07 to sticking with it and not taking maybe an offer that they want. Our obligation, of course, is to Mrs. Booker.

Do which have Mrs. Booker's agreement that under all circumstances she's going to go to a jury verdict on this 15:15:22 case? We can't possibly do that. That would be something probably -- I mean, we don't. Even if we did, it could change in the middle of that trial.

And that's why I have some of these other topics on there. I think it's important -- we've got to have a little 15:15:38 bit of -- I don't want to call it chaos, but the parties have to feel the heat of more than just one case going to trial next year. Both plaintiffs and defendants. That's why I wanted to talk about the early remands. That's why I wanted to talk about maybe having additional bellwether cases ready 15:15:54 to go to trial.

We were able to talk -- discuss with Judge Brodman the idea of we've got this trial date in August reserved. We've got three other cases that are basically on the same track. We're going to -- all four of those cases are going to 15:16:09 be getting ready to go to trial --

THE COURT: Well, that, to me, is a very different situation. He does not have an MDL. He hasn't gone through a bellwether process. He's got a collection of cases he needs to resolve.

15:16:20 I'm interested in what the defendants have to say on

15:16:24 this idea of sort of selectively settling bellwether cases.

MR. NORTH: Your Honor, first of all, we don't need to argue the point now, but I disagree with a lot of what Mr. Lopez said about our settlement history. We've settled 15:16:40 many, many cases with many attorneys well in advance of trial dates.

Now, with regard to the concern the Court raises, that is a concern. But it's a concern on both sides of the table.

15:16:50 Many MDL judges in the past have bemoaned the fact that defendants have settled cases in an effort to manipulate the bellwether pool, and many judges have bemoaned the fact that the plaintiffs have dismissed cases on the eve of trial in a bellwether context because they're cases they didn't want 15:17:10 to try. It is a problem on both sides of the fence. It does happen sometimes.

We certainly are not intending to do that. We are happy with the bellwether selections. We are committed to the process to try some bellwether cases.

15:17:28 As Mr. Lopez says, can you never say never? I don't think you can. But that's not the intention now of Bard, to pull out the rug from Booker, just as I hope it's not his intent to dismiss Booker at the last minute or dismiss Jones at the last minute. So it is certainly not our intention to 15:17:46 try to manipulate this process.

15:17:52 MR. LOPEZ: Well, Judge, can I just -- if we're going to talk about historical, the reason we have an MDL is because when this was 150-case litigation, after trying a case for 11 days in front of Judge Jones, after the defense verdict he got 15:18:09 against someone completely different than us four years ago here in Arizona, and after getting the motions in limine and *Daubert* and motions for summary judgment on a half dozen other cases, and now having 10 MDL cases, I mean now MDL cases ready to go to trial as soon as they get remanded, Bard said, We 15:18:27 have enough history here to settle your cases, and then three times, without any explanation, they just said, We're not interested in discussing settlement with you. And now we're setting the next six cases for trial, which is when I said I can't do this for 150 different people with five law firms; 15:18:44 we've got to get an MDL. So that's why we have an MDL, is because I think that was -- I've never had a bellwether process like we had before an MDL that basically described what these cases were about and basically what the risks were to both sides.

15:19:02 So I bring that up because I -- my personal opinion is one bellwether trial is not going to change what happens to the other 3,000 plaintiffs. If Bard's plan is to try three or four cases a year, then, I mean, I -- my grandson is not -- he'll be too old some day to try the last case. So --

15:19:31 THE COURT: Well, nobody's ever suggested, Mr. Lopez,

that we're going to bellwether trial every case in the MDL. My view is we'll do five bellwether trials, I'll pick a sixth if we need it, and then we're done with bellwether trials. Assuming we can try all those cases.

15:19:49 You've got a fair representative. If you can't settle it on that basis, we send them back to their districts because we've tried hard in this setting not only to make decisions on the common issues and get those resolved, but we've tried a sample of cases to help inform the parties of 15:20:04 how they play in front of a jury. If that doesn't help you settle it, we just don't keep trying bellwether cases here. That's not what an MDL is for. We send them home, and you can deal with them in their home districts.

MR. LOPEZ: Right.

15:20:16 THE COURT: Which is why the notion was a surprise to me that we may in some way pick off some of these five cases that we've gone through a fairly lengthy process to identify for the bellwether process.

MR. LOPEZ: Your Honor, that's why I'm suggesting 15:20:29 what I suggested. The plaintiffs' position in the joint statement. We have to have some kind of fail-safe process in place in the event -- it's going to happen on some of these cases. If we --

THE COURT: What's going to happen?

15:20:44 MR. LOPEZ: That some of these cases are going to get

15:20:47 picked off and get resolved before we get a jury to tell us --

THE COURT: Some of the bellwether cases?

MR. LOPEZ: Possibly. I mean, I can't predict that one way or another. All I can tell you is we want to try the 15:20:57 Booker -- we'll try every bellwether case. The lawyers want these cases to go to verdict because we think that is going to be instructive and it's going to serve the purpose of what you want to get from a bellwether trial.

But we can't -- our ethical obligation is to the 15:21:14 plaintiff. And I don't -- I can't predict what Bard's going to do once these cases are in the middle of trial. What I'm suggesting to you is that happens all the time. And in order to have kind of a backup to that, kind of a fail-safe system in place, we've got 10 cases that are -- we're going to talk 15:21:34 about, I hope, today that are pretty close to trial. One of them, we're just waiting for our judge in Jacksonville to make a ruling on motions in limine.

We should talk about that. And even counsel in their papers said the spring of this year we can remand those cases 15:21:51 back.

I think what I'm trying to say to Your Honor is five cases may not do it. The five bellwether cases set here may not actually get us a case to trial. But I think 15 or 20 would. Whether it be in Arizona, whether it be here, whether 15:22:05 it be --

15:22:06 THE COURT: I will tell you, Mr. Lopez, if we have cases settling in the middle of trial like that, I'm going to strongly tempted to say we're done, this bellwether process is not working, these are all going back to their districts. 15:22:19 Because the whole idea here -- we don't do trials in MDL's. The whole notion behind a bellwether trial process is to, while we're together, give you a fair sampling of how the defenses and the claims play. And if that's not working because parties are withdrawing cases or settling cases in the 15:22:37 bellwether process, my view is we shouldn't be playing that game. We should finish the work of the common issue discovery, the common issue rulings, and terminate the MDL.

MR. LOPEZ: Your Honor, let me make sure that I'm making myself clear. We -- the plaintiffs 100 percent endorse 15:22:53 what you just said. We want a bellwether process that works. We do. And if it doesn't work, at no fault of maybe either of the parties, we're prepared for these cases to be remanded.

But, look, I understand that the idea of having an MDL and having an MDL judge is to prevent that from happening. 15:23:16 I mean, we've brought all the cases here to relieve the pressure in 50 other states and I don't know how many hundreds of different courthouses. We get it. And the plaintiffs want the case to resolve here. And, again, we agree that the bellwether process is what we hope will make that happen.

15:23:35 I'm just -- my suggestion to you is one or two cases

here might get that done, and you don't necessarily have to remand everything. The idea is to make sure we get maybe three or four cases, different cases, maybe on different products, to a jury verdict. It may not happen here. We want it to. We're happy to try five cases here next year. But I think it would be -- it would certainly serve the purpose for which Your Honor just stated, that in the event that that doesn't happen, say in March or May, for whatever reason, we've got five or six other cases that are putting pressure on both sides. One will have a greater opportunity to -- I think the Austin case probably would have gone to trial. I wish it had. I think it was heading in that direction. I know that wasn't a federal court case, wasn't an MDL case, but the Austin case or a lot of cases like that in this MDL certainly would have been instructive.

I hear what you're saying. I understand that the obligation is try to get everything resolved here. The plaintiffs are fully committed to that process. I just want you to know that. We're not asking for remands, but I understand if you have to do it, I mean, that's -- we can't drag this thing on forever in this MDL because we can't possibly try 3,000 cases here.

THE COURT: Any other comments?

MR. NORTH: Your Honor, I'll just reiterate what I said earlier, that we are committed to the bellwether process.

15:25:10 THE COURT: Well, I am not going to start us down the road of bellwether group 2 at this point. We've got five bellwether cases with a sixth to be selected. There's no way we're going to get those six cases tried any sooner than the 15:25:22 end of 2018, if we can get it done in 2018, and that will require the help of some other judges, as I've already indicated.

So we are more than a year away from a bellwether group 2, if we are even going to do that. And as I've 15:25:38 indicated, I'm not sure there's a point for that. These seem to me to be pretty representative cases, and if these can't help you settle it I'm not sure we should spend more time here trying to do that.

So I'm not going to do a bellwether group 2 at this 15:25:52 point.

We've got our first two cases. I'm going to plan on Booker going and not settling. We're going to do the motions in limine in light of that plan. It's still going to be a challenge to get all of the *Daubert* motions decided by then, 15:26:08 but I'm going to do my best so we don't to have bump that trial date.

And we'll just have to see how we're doing on that come January, probably.

In terms of the mature cases, I don't see why we 15:26:23 should be doing case-specific discovery in this MDL. It seems

15:26:27 to me if there is additional case-specific discovery to be done in cases in the MDL, that gets done in the home court. We were holding those mature cases until we got the *Daubert* motions decided and the preemption motion decided in cases 15:26:43 that could affect them. Once we finish that process, my understanding has been we ought to go ahead and remand them, unless that's going to cause you problems in trying the bellwether cases because you're running up against another trial in one of those districts. But that doesn't sound very 15:27:00 likely. But I don't see a reason we should start case-specific discovery here. Is there a reason we ought to do that in this MDL?

MR. LOPEZ: I think -- let's just assume that the cases are -- have been remanded. I don't think it makes any 15:27:14 difference whether or not they're still sitting here. Whether or not the judge who originally had the case is now -- or has officially received the case back in remand.

My idea was if these cases are going to be remanded and Your Honor thinks it's a good idea to do that, why not 15:27:32 have them trial ready? Why not -- if there's a deposition here or there that needs to be taken of a lay witness or there's an expert still pending with respect to that case, why not, by the spring of this year, whatever date it is that we -- I think we could probably agree they could be remanded, 15:27:51 why not just have them ready to go? I mean, just send it back

15:27:55 to the judge in these 10 different districts, and we'll just get on their trial docket.

THE COURT: If you guarantee there's no discovery issues I'll have to rule on, I'm all for that.

15:28:09 I'm not going to say that's a joke.

MR. LOPEZ: Well, I understand that.

THE COURT: That's one of my concerns. If one of those cases blows up over a discovery issue, we just added to a pretty heavy workload in this court. Maybe it won't. You

15:28:24 have had very few discovery issues. You guys have done a great job, in my view, of handling discovery.

MR. LOPEZ: I kind of have an idea.

THE COURT: Okay.

MR. LOPEZ: Why don't we just do it. If we do, we

15:28:35 just save that. In other words, let's say we have -- we've gone through this process, we've got issues with a witness, we've got issues -- at least that deposition's been taken. At least that discovery's been sought. And now when the judge gets it back, it's not, well, now let's take the depositions

15:28:51 and see how big of a fight it's going to be to get certain evidence or get certain testimony.

At least -- I guess what I'm trying to say, Judge, let's try to get -- they're just sitting there languishing. Some of these cases are five years old. Most of them are four

15:29:05 years old. One of them was filed in 2012. Most of them were

filed in 2013. And like I said, we've designated, we've stipulated these are early remands because they had made so much progress to get towards -- I think we may have had trial dates in most of them, if not all of them.

At the very least maybe we can sit down with counsel and see if we can come up with or devise some kind of a plan to at least move the ball closer to at least the 20-yard line on these cases so that if we send them back there's a minimum amount of work to be done for the remand judge to set them for trial.

I'm just suggesting that. Because like I said, some of them have motions in limine that have already been heard. Some we're still playing with experts.

THE COURT: All right.

MR. NORTH: Your Honor, there certainly could be no guarantee that there wouldn't be discovery issues. But not only would it be a distraction -- of course, that's most important, we don't need distractions for the Court right now -- but I think it will be a distraction for the parties to run around and take a update deposition of a plaintiff.

Let's be realistic. We're only talking about three to four more months probably at most when these cases are going to be ripe for remand after the *Daubert* rulings are made.

I think virtually none of these federal judges

15:30:25 sitting around the country in these eight or nine cases are going to be able to put us on an immediate docket. They've got full trial schedules, just like most members of the federal judiciary. There's going to be lag time. There's
15:30:39 going to be plenty of time to do what little discovery is necessary in front of those judges, who then can monitor and handle the situation.

And I just think we all need to focus here on this first bellwether trial in March, and not have that distraction
15:30:51 right now.

THE COURT: All right. I will think about this issue and I will include a decision on it in the ruling or the order that comes out after today's hearing.

What I do want to do is set a final pretrial
15:31:10 conference for the Booker case. We're scheduled to start on March 13th.

The tension is that I want it to be far enough -- or close enough to the trial that I have time to get all of these *Daubert* motions decided, but far enough in advance of trial to
15:32:23 inform you for your trial preparation. So my inclination would be to set it about two weeks before trial. That would be where I would hear the motions in limine. That would leave you a couple of weeks to do your final preparation in light of my ruling, but yet it wouldn't crowd any more of February that
15:32:41 we will probably have to spend on some of these *Daubert*

15:32:44 motions.

Do you have any thoughts on that approach?

MR. LOPEZ: I mean, I know there's one date at the end of February where it's a personal family thing with some 15:32:56 surgery, but if we can do it before that date, I think it's like the 25th or 26th of February, which is maybe a little bit more than two weeks before the 13th. If we could push it maybe two days before that date.

THE COURT: I was thinking of Friday the 23rd.

15:33:11 MR. LOPEZ: Yeah, that's works.

THE COURT: Does that work?

MR. NORTH: Yes, Your Honor.

THE COURT: All right. So let's set it for Friday the 23rd at 2:00 p.m.

15:33:29 Now, I will tell you I am scheduled that day to be in the middle of a two-week environmental trial that has not settled for two and a half years. It's a pretty hard fight between some companies and the federal government. If it goes, I won't be able to do it, I'll have to push it closer to 15:33:49 trial. But they're having a big mediation in early December and that case may resolve, in which event we'll have that date available. So I'll set that date, but it may get bumped if that trial goes.

You all raised in the joint report the idea of me 15:34:09 setting a time for you to meet and talk. You guys can do

15:34:16 that. And I'm all for you sitting down and stipulating on foundation issues, agreeing on every evidentiary issue you can.

I will tell you that I do -- I think I might have 15:34:29 mentioned this to you before -- I do typically set time limits, hour time limits for civil trials. I'll do that based on the assumption of a three-week trial. But I'll do that after I get your final pretrial -- proposed final pretrial order, which will be filed in advance of that February 23rd 15:34:46 final pretrial conference.

We will send out an order that tells you what we need for that final pretrial conference, and one of it will be an estimate of how that time ought to be divided up. But I will keep track of your time. I'll tell at noon and at the end of 15:35:02 the day how you're doing so you can budget things as we go through the trial.

My thought would be with a three-week jury trial, that we would probably seat a jury of nine people. That way we can lose three and still have six to deliberate at the end, 15:35:23 but obviously if we don't lose any, the nine deliberate at the end.

Do you have -- we don't need to decide that finally now, but do you have strongly different views on that issue?

Well, we can think more about that.

15:35:41 Is there any sense that we need a jury questionnaire

15:35:45 in this case as opposed to just typical voir die?

MR. LOPEZ: I think we want a questionnaire, Your Honor.

THE COURT: Why? What is your thought? I typically 15:35:56 don't do it. I've done it in a half dozen cases where there were particularly sensitive issues, but I'm interested in your thoughts as to why we need it here.

MR. LOPEZ: I guess the best response I can give you is we customarily do do those in these complex cases.

15:36:14 Does Your Honor have, like, his own standard set of voir dire questions?

THE COURT: Well, yeah, I do. I mean, they're pretty generic. Typical voir dire questions.

MR. LOPEZ: And would the alternative to a 15:36:28 questionnaire be submitting to you additional questions that parties --

THE COURT: Yeah, that's one -- one of the things I would ask you for in preparation for that final pretrial conference is your proposed voir dire questions. And I would 15:36:42 go through and decide which to ask. I typically ask, and let you ask follow-up questions.

But if you think we need a jury questionnaire, I'm happy to consider that. The logistics are that we need to have that finalized about a month before trial.

15:36:59 Is that right, Traci? I think it's about a month,

15:37:03 five weeks.

Because it's got to be mailed out by the jury office, it's got to be mailed back, they've got to follow up, we've got to then get it to you, we then have to have a hearing
15:37:12 where we talk through what we've learned and who we're going to knock out and who we're not. It just adds time to getting ready for trial.

MR. LOPEZ: Can we meet and confer on that, Your Honor --

15:37:23 THE COURT: Absolutely.

MR. LOPEZ: -- maybe come together with a stipulated questionnaire that you think is okay.

THE COURT: Why don't you -- let's make that one of the topics you'll meet and confer about between now and the
15:37:33 next hearing date, which I think is December 15th. And if you think there should be a questionnaire, I would encourage you to come up with a proposed questionnaire so I can look at what you think is needed. That will leave us time, if we decide to go down that road, to get it out before the end of January,
15:37:50 and I'll decide then whether it's needed or whether voir dire will do.

MR. LOPEZ: One other suggestion, Your Honor, to help maybe expedite this process, I understand the biggest burden is you preparing for the hearing, not the two hours we spend
15:38:09 here, so maybe this isn't going to help much, but maybe

15:38:13 counsel and I can get together and talk about some of these motions where we can just submit on the papers and you can just rule on those.

THE COURT: That's fine. I mean, that does -- the 15:38:26 advantage then is I can work on it and issue a ruling and I don't have to wait two weeks for the argument, by which time I've forgotten 75 percent of what I read.

But yeah, it really just does save the hearing time. I don't know that we'll be able to get more motions decided 15:38:42 that way, but we'll get them out more quickly if we do that.

MR. LOPEZ: We'll talk about it, then, and see if we can.

THE COURT: Okay. All right. So I then will plan on the remaining four motions we had scheduled today plus the 15:39:01 next two for December 15th, but I'll let you know if I'm falling short of that as we get close to it.

We'll get the order out setting the final pretrial conference.

In fact, Traci, I'll just put that into this case 15:39:15 management order, if you could just send me the template.

THE COURTROOM DEPUTY: Okay.

THE COURT: I want to go on the assumption that we're trying Booker in March. If there's changed thinking between now and the December 15th hearing, we can always move Jones up 15:39:37 and do it. And all of this is assuming I can get through

these motions by March, which I'm going to do my best to do, but there are a lot of them.

What else do we need to talk about today? Well, yeah, I'm going to decide the mature case discovery issue after I think about it a bit more.

Do you have other matters we need to address on the plaintiff side?

MR. LOPEZ: No, Your Honor, not on the plaintiff side.

MR. NORTH: Nothing for the defendants, Your Honor.

THE COURT: Okay. I should get you a decision on these two motions argued today within the next two weeks. Maybe sooner than that.

Thank you all.

MR. NORTH: Thank you.

MR. LOPEZ: Thank you, Your Honor.

(End of transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 27th day of November, 2017.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter